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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,618	12/17/2001	Guido Henning	Le A 35 010	1214

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT PAPER NUMBER

1642

DATE MAILED: 11/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/022,618

Applicant(s)

HENNING ET AL.

Examiner

Susan Ungar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 17 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-11 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

1. Claims 1-11 are pending in the application and currently under consideration.
2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
3. It is noted that the claims of the instant application have been determined to include linking claims. Claim 1 links Groups (A1-A74, C1-C4) (B1-B542,250). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 1 and 2. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**Groups A1-A26.** Claims 1-3, 9-11 are drawn to a method for detecting tumor cells in uterine cervical smears by simultaneously detecting at least two polypeptide molecular markers in a cell, as disclosed in the specification, wherein the markers are selected from at least one of tumor suppressor genes, apoptosis genes, proliferation genes, repair genes and viral genes, wherein detection is automated, classified in Class 435, subclass 7.1. It is noted for

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Applicant's convenience that the number of combinations of groups in claim 2 has been determined in the following fashion, that is  $2^N - (N+1) =$  number of groups. Since there are five groups claimed, the Groups were calculated as  $2^5 - 4 = 26$ . It is further noted for Applicant's convenience that **this is not an election of species requirement**.

**Groups A27-A52.** Claims 1-3, 9-11 are drawn to a method for detecting tumor cells in uterine cervical smears by simultaneously detecting at least two polynucleotide molecular markers in a cell, as disclosed in the specification, wherein the markers are selected from at least one of tumor suppressor genes, apoptosis genes, proliferation genes, repair genes and viral genes, wherein detection is automated, classified in Class 435, subclass 6. It is noted for Applicant's convenience that the number of combinations of groups in claim 2 has been determined in the following fashion, that is  $2^N - (N+1) =$  number of groups. Since there are five groups claimed, the Groups were calculated as  $2^5 - 4 = 26$ . It is further noted for Applicant's convenience that **this is not an election of species requirement**.

**Groups A53-A74.** Claims 1-3, 9-11 are drawn to a method for detecting tumor cells in uterine cervical smears by simultaneously detecting at least two molecular markers, one of which is a polynucleotide and one of which is a polypeptide in a cell, as disclosed in the specification, wherein the markers are selected from at least one of tumor suppressor genes, apoptosis genes, proliferation genes, repair genes and viral genes, wherein detection is automated, classified in Class 435, subclass 6 and Class 435, subclass 7.1. It is noted for Applicant's convenience that the number of combinations of groups in claim 2 has been determined in the following fashion, that is  $2^N - (N+1) =$  number of groups. Since there are five groups claimed, the Groups

were calculated as  $2^5 - 4 = 26$ . It is further noted for Applicant's convenience that **this is not an election of species requirement.**

It is noted that Applicant must elect a single invention of a single group of two or more marker groups from Groups A1-A74 for examination.

4. For each of the inventions A1-A74 above, restriction to one of the following is also required under 35 USC121. Therefore, if Applicant elects one of inventions A1-A74, election is required of one of inventions A1-A72 **and** one of inventions B1-B542,250. It is noted that this is not an election of species requirement in that each of the linked groups consists of one of inventions A1-A72 above **and** one of inventions B1-B262,125 below. It is noted for Applicant's convenience that the number of combinations of groups in claim 3 has been determined in the following fashion, that is  $2^N - (N+1) =$  number of groups. Since there are eighteen groups claimed, the Groups were calculated as  $2^{18} - 19 = 262,125$ . Since these markers are drawn to both polynucleotides and polypeptides, as disclosed in the specification, the number of groups is  $262,126 \times 2$  which equals B542,250. It is further noted that Applicant is required to make election of the specific markers as they are drawn to the election of Groups A1-A52. For example if only the Group drawn to polynucleotide viral genes is elected in Groups A1-A74, then the combination election from Groups B1-B542,250 may only include specific DNA from specific HPV subtypes.

**Groups B1—B542,250.** Claims 1-3, 9-11 are drawn to a method for detecting tumor cells in uterine cervical smears by simultaneously detecting at least two molecular markers in a cell, as disclosed in the specification, wherein the markers are selected from at least one of her2/ner, p1, p53, MN, mdm-2, bcl-2, EGF receptor, specific DNA from the HPV subtypes 6, 11, 16,

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18, 20, 31, 33, 35, 45, 51, 52, wherein detection is automated, wherein the polynucleotide markers are classified in Class 435, subclass 6 and the polypeptide markers are classified in 7.1. It is further noted for Applicant's convenience that **this is not an election of species requirement**. It is noted that claim 4 will be examined as it is drawn to the elected invention.

**Group C1-C2.** Claims 1 and 5 are drawn to a method for detecting tumor cells in uterine cervical smears by simultaneously detecting at least two polypeptide markers and then three markers classified in Class 435, subclass 7.1.

**Group C3-C4.** Claims 1 and 5 are drawn to a method for detecting tumor cells in uterine cervical smears by simultaneously detecting at least two polynucleotide markers and then three markers classified in Class 435, subclass 6.

5. It is noted that the claims of the instant application have been determined to include linking claims. Claim 6 links Groups (D1-D2). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 6. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the

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provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**Group D1**, claims 6-8 are drawn to a kit comprising at antibodies to at least two molecular markers in a cell, classified in class 530, subclass 3871.

**Group D2** claims 6-8 are drawn to a kit comprising at polynucleotide probes to at least two molecular markers in a cell, classified in class 530, subclass 3871.

6. The inventions are distinct, each from the other because of the following reasons:

Inventions (A1-A74, C1-C4) (B1-B542,250) are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Inventions D1-D2 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

The inventions of Groups A1-A26/A53-A74/B1-262-125/C1-C2 and D1 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the antibody product as claimed can be used in a materially different process such as producing anti-idiotypic antibody.

The inventions of Groups A27-A74/B262,125-B524,250/C3-C4 and D2 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process

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for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the nucleic product as claimed can be used in a materially different process such as producing polypeptides which are encoded by said nucleic acids.

Inventions A1-A74, B1-B542,250 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (*MPEP* § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for screening for different markers. Thus the claims are distinct as required by *MPEP* 806.05(c).

7. Because these inventions are distinct for the reasons given above have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed



petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

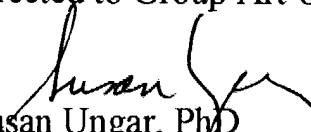
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this

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application, all further correspondence regarding this application should be directed to Group Art Unit 1642.



Susan Ungar, PhD  
Primary Patent Examiner  
August 9, 2004